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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,413	11/17/2005	Nobushige Doisaki	052572	5903
<div>38834      7590      06/27/2007 WESTERMAN, HATTORI, DANIELS &amp; ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036</div>			<div>EXAMINER WINSTON, RANDALL O</div>	
			<div>ART UNIT 1655</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 06/27/2007</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/535,413

**Applicant(s)**

DOISAKI ET AL.

**Examiner**

Randall Winston

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 0505.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's election of species of c) a polyunsaturated fatty acid ester and the election of species of sesamol in its response on 05/22/2007 is acknowledge. Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Readable claim 1-3 and 5-20 will be examined on the merits.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5-20 are rejected under 35 USC 103(a) as being unpatentable over Kataoka et al. (US 6235331) or and Granata (WO02/058793) in view of Chavali et al. (US 20010031275, DWPI Abstract), Maguire et al. (DWPI Abstract, 1995-054394), Chen et al. (US 20020156051, DWPI Abstract) and Wechter (US 6242479).

Applicant claims a composition comprising an organic substance having a double bond (i.e. eicosapentaenoic acid ethyl ester (EPA) or docosahexaenoic acid ethyl ester (DHA)) which contains an antioxidant comprising an antioxidative sesame component (i.e. sesamol) which is purified from sesame or synthesized and either ascorbic acid or ascorbyl fatty acid ester and further comprising a tocopherol.

Both Kataoka or Granata teach that eicosapentaenoic acid ethyl ester (EPA) or docosahexaenoic acid ethyl ester(DHA) treats cardiovascular disorders (see, e.g. in Kataoka the entire document including column 1 lines 24-39 and in Granata the entire document including abstract). [please note that Katoka teaches that eicosapentaenoic acid ethyl ester (EPA) or docosahexaenoic acid ethyl ester(DHA) is obtained from fish oil. Moreover, the claimed eicosapentaenoic acid ethyl ester (EPA) or claimed docosahexaenoic acid ethyl ester(DHA would also intrinsically be of an organic substance with a double bound]. Kataoka or Granata, however, does not expressly teach the other active ingredients such sesamol, ascorbic acid or ascorbyl fatty acid ester and tocopherol are contained within its composition to treat cardiovascular disorders.

Chavali beneficially teaches that sesamol treats cardiovascular disorders (see, e.g. DWPI abstract). [please note that elected species of the pure sesamol intrinsically has the characterized in claim 7]

Maguire beneficially teaches that ascorbyl palmitate treats cardiovascular disorders (see, e.g. DWPI abstract).

Chen beneficially teaches that ascorbic acid treats cardiovascular disorders. (see, e.g. DWPI abstract).

Wechter beneficially teaches that tocopherol treats cardiovascular disorders. (see, e.g. entire document including abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify either Kataoka or Granata composition's teachings to

include the active ingredients of sesamol, ascorbic acid or ascorbyl fatty acid ester and tocopherol as taught by Chavali, Maguire, Chen and Wechter within Kataoka or Granata composition's teachings because the above combined teachings would create the claimed composition to treat cardiovascular disorders. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose..." The adjustments of other conventional working conditions (i.e. the claimed active ingredient's amounts within its composition, the substitution of one form of the composition for the another and fish oil form), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.


Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note that the patentability of a product does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE  
PRIMARY EXAMINER